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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **BIGGADIKE, et. al.**

Serial No.: **10/067,020**

Group Art Unit: **1616**

Filed: **02/04/2002**

Examiner: **BADIO**

For: **FORMULATION CONTAINING ANTI-INFLAMMATORY ANDROSTANE DERIVATIVES**

Director of the United States Patent and Trademark Office  
Alexandria, VA 22313

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

☒ Copies of the references are enclosed: **3-7**

☐ Copies of the references were submitted in parent application Serial No. \_\_\_\_\_ (37 CFR 1.98(d))

☐ A copy of the International Search Report which issued on International Application No. \_\_\_\_\_ is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

A. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

OR

☐ The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).

B. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,

whichever occurs first.

☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

☐ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$240.00).

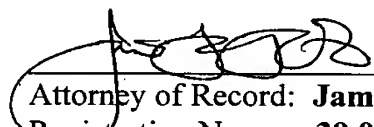
C. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the

issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
  - ☐ Applicant hereby petitions for the consideration of the accompanying Information Disclosure Statement. 37 CFR 1.97(d)(ii).
  - ☐ The petition fee set forth in § 1.17(i)(1) (\$130.00) is submitted herewith.
- ☒ Please charge any required fees to Deposit Account No.07-1392.
- ☐ A duplicate copy of this paper is attached.

Respectfully Submitted,

 28 July 2003  
Attorney of Record: **James P. Riek**  
Registration No.: **39,009**  
Telephone: **(919) 483-8022**



IN THE UNITED STATES PATENT OFFICE

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Applicant : Biggadike et al.  
Application No. : 10/067,020  
Filed : February 4, 2002  
Title : Formulation Containing Anti-inflammatory Adrostane Derivatives.

Grp./A.U. : 1616  
Examiner : Badio, Barbara

Docket No. : PG4733

Commissioner of Patents  
Washington DC 20231

COMMUNICATION

Applicant would like to thank the examiner for discussing this case via a telephone interview on July 25, 2003. In the interview, the applicant's representative and the examiner discussed the interrelationship of co-pending applications 09/958,050; 10/066,964; 10/067,020; 10/067,010; 10/066,836; 10/200,364; 10/281,735 and 10/241,658, and 10/066,951 and US Patent 6,537,983.

As promised, Applicant has included herewith an information disclosure statement and Form 1449 listing the co-pending applications, as well the '983 Patent. At the time of our discussion, each of these co-pending applications, with the exemption of the '951 application, were in the examiner's possession. Also included in the IDS are a list of references cited in a PCT Search Report recently issued in a foreign counterpart to this application.

In the telephone interview, the examiner stated that potential "obviousness-type" double patenting issues might exist between the claims under examination and the claims of US Pat. No. 6,537,983; US Serial Nos. 09/958,050; 10/067,010; 10/200,364; and 10/241,658.


Applicant respectfully disagreed with the examiner's position that any obvious-type double patenting is here presented. Applicant indicated that the claims of this

application are patentable distinct over the claims in each of the other cases. As such, it is applicant's position that no obviousness-type double patenting issues exist in this case. However, solely in an effort to further prosecution, and without prejudice, applicant agreed to submit the terminal disclaimers requested by the examiner. Applicant agreed to file these disclaimers because they have no effect on the actual term of any patent resulting from this application. Patents resulting from each of the disclaimed cases would have expire on the same date as a patent issuing from this application, even in the absence of the disclaimer. In filing these disclaimers, applicant specifically reserves the right to address any double patenting issues in the future, should the need arise. Applicant makes particular note of MPEP 804.02 II and established case law findings of the Federal Circuit, in Quad Environmental Technologies v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), that the filing of a terminal disclaimer to obviate a rejection based on a non-statutory double patenting is not an admission of the propriety of the rejection. The filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.

In light of these terminal disclaimers, all issued raised by the examiner in the telephone interview have been addressed. As such, the claims are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,



James P. Riek

Dated: 27 July 2003

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